a catheter having a wall section adapted to permit said CSF to flow therein, said catheter adapted for introduction through an opening in said patient through which a region of CSF is accessible; and

a sensor located within said catheter such that said CSF is permitted to flow adjacent the tip of said sensor;

whereby said sensor is capable of permitting the monitoring of at least one characteristic of said CSF over time.

37. (New) The apparatus of claim 36, whereby said catheter is a dual lumen catheter comprising a first lumen and a second lumen.

38. (New) The apparatus of claim 37, whereby said sensor is housed in said first lumen and said CSF is withdrawn through said second lumen.

39. (New) The apparatus of claim 36, whereby said characteristic monitored is selected from the group consisting of pH, partial oxygen pressure, temperature, carbon dioxide concentration, and combinations thereof.

40. (New) The apparatus of claim 36, further comprising:

equipment for monitoring, storing, and, comparing data of said characteristic from said sensor over time.--

REMARKS

Applicants respectfully request reconsideration of the subject application in light of the above amendments and the following remarks. The specification has been amended. Claims 1-9 have been canceled. Claims 10-40 have been added. No new matter has been added to the present application.

An abstract on separate sheet has been included as required by 37 CFR 1.72(b).

The specification has been amended to include section headings.

Claims 7-9 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants respectfully traverse this rejection and argue that claims 7-9 do particularly point out and distinctly claim Applicants' invention. For instance, in claim 7, "[t]he use of measured changes of CSF pH with time" is the step involved in the process of diagnosis or therapy of neurological injuries. In claim 8, "[t]he use of means for monitoring the change of CSF pH over time" is the step involved in the process of manufacture of the apparatus. In claim 9, "[t]he use of means for monitoring the change of CSF pH with time" is the step involved in the manufacture of the apparatus. In any event, Applicants have canceled claims 7-9. Accordingly, the amendment renders the rejection moot.

Claims 1-9 stand rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicants regard as their invention. Specifically, claims 1-9 stand rejected for failing to provide sufficient antecedent basis for terms used in claims 1-9. Claims 1-9 have been canceled, and, therefore, this rejection is moot.

Claims 7-9 stand rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,904,237 to Janese (hereinafter "Janese"). The Examiner claims that "the apparatus and method [of Janese] can be used for monitoring the current status of a patient by monitoring the physical and chemical parameters of the cerebrospinal fluid." (Office Action, p. 5, paragraph 9).

Applicants traverse the rejection. Janese does not disclose the present invention. The Examiner admits with regard to a later rejection that "Janese does not teach that the pH probe is inserted into a patient's brain ventricle." (Office Action, p. 7, paragraph 12). Applicants agree, and, in addition, contend that Janese does not teach or suggest monitoring of any CSF characteristic

within the body of the patient. Further, Janese does not teach or suggest placing a sensor within a catheter located in a region of CSF to measure CSF characteristics. In any event, claims 7-9 have been cancelled, and, therefore, the rejection is moot.

Claims 1-5 stand rejected under 35 U.S.C. 103(a) as being obvious over Janese. The Examiner claims that "the apparatus and method can be used for monitoring the current status of a patient by monitoring the physical and chemical parameters of the cerebrospinal fluid." (Office Action, p. 6, paragraph 11)

Janese does not suggest the present invention. Unlike the present invention, Janese does not suggest placing a sensor into a catheter having a flow section capable of permitting the CSF to flow therein. Rather, Janese appears to suggest monitoring of CSF outside the body. (Janese, Col. 6, line 53 to Col. 7, line 15). The Examiner's states that Janese discloses a "probe [] received in the ventricle of the patient. (Figs. 4-6 of Janese). " (Office Action, p. 7) Janese actually discloses a "cannula 99 which punctures the spinal canal providing a conduit for a catheter 93 which indwells in the subarachnoid compartment of the spinal canal 33." (Janese, col. 7, lines 37-40) Janese does not disclose a sensor received in the body of the patient as is disclosed in the present invention. Nevertheless, claims 1-5 have been canceled, and, therefore, this rejection is moot.

Claim 6 stands rejected under 35 U.S.C. 103(a) as being obvious over Janese in view of U.S. Patent No. 4,903,707 to Knute et al. (hereinafter "Knute") and U.S. Patent No. 4,830,849 to Osterholm (hereinafter "Osterholm").

The references, either alone or in combination, do not suggest the present invention. The Patent and Trademark Office's burden of establishing a prima facie case of obviousness is not met unless "'the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art.'" In re Bell, 26 U.S.P.Q.2d 1529, 1531 (Fed.

Cir. 1993) (quoting In re Rinehart, 189 U.S.P.Q. 143, 147 (C.C.P.A. 1976)). Specifically, Janese does not suggest placing a sensor into the flow section within a catheter within a body to enable the CSF to flow adjacent the tip of the sensor so that the sensor may sense at least one characteristic of the CSF. Knute does not suggest monitoring any chemical characteristics. Osterholm does not suggest monitoring within the body CSF characteristics. Any of the above references in combination would not disclose the present invention. In any event, claim 6 has been canceled, and, therefore, this rejection is no longer applicable.

Attached hereto is a marked-up version illustrating the changes made to the specification and claims by virtue of the current amendment. The attached page is captioned **"Version with markings to Show Changes Made."**

In view of the foregoing, Applicant respectfully submits that the application as amended is in condition for allowance and favorable action is requested. Should the Examiner believe any issues are outstanding he is encouraged to contact the undersigned at (816)474-6550.

The Commissioner is hereby authorized to charge any additional fee which may be required, or credit any overpayment, to Deposit Account No. 19-2112. A duplicate copy of this response is enclosed.

Respectfully submitted,

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JHA

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Version with Markings to Show Changes Made

In the Specification

An abstract has been added on page 10 as follows:

A method and apparatus for predicting the outcome of head injury trauma by monitoring cerebrospinal fluid (CSF) characteristics, preferably my monitoring the pH of CSF. The apparatus includes a catheter with a wall section adapted to permit CSF to flow therein , and a sensor located within the catheter such that the CSF is permitted to flow adjacent the tip of the sensor.

The following headings and text have been added after the title:

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

Not applicable.

CROSS REFERENCE TO RELATED APPLICATIONS

Not applicable.

BACKGROUND OF THE INVENTION

The following heading has been added after the second paragraph on page 1:

BRIEF SUMMARY OF THE INVENTION

The following heading has been added after the first paragraph on page 3:

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

The following heading has been added after the seventh paragraph on page 3:

DETAILED DESCRIPTION OF THE INVENTION

In the Claims

Claims 1-9 have been cancelled without prejudice or disclaimer.

Claims 10-40 have been added:

10. A method of monitoring the cerebral cellular environment of a patient for prognosis and for providing information for treatment, comprising:

providing an opening in the skull of said patient;

inserting a catheter through said opening into a region of cerebrospinal fluid (CSF) within said skull of said patient, said catheter having a flow section capable of permitting said CSF to flow therein;

positioning said flow section of said catheter into said region of CSF;

placing a sensor into said flow section within said catheter to enable said CSF to flow adjacent the tip of said sensor so that said sensor may sense at least one characteristic of said CSF; and

monitoring the changes of said characteristic of said CSF.

11. The method of claim 10, whereby said region of CSF is a cerebral ventricle.

12. The method of claim 10, further comprising:

fixing said catheter in place in said opening of said skull to prevent movement of said catheter relative to said opening in said skull.

13. The method of claim 10, whereby said inserting step further comprises:

inserting said catheter into said region of CSF until expression of said CSF indicates said catheter has reached said cerebral ventricle.

14. The method of claim 10, further comprising:

connecting said catheter to an extension tube; and

locking said sensor within said catheter.

15. The method of claim 14, further comprising:

draining said CSF through said catheter; and

monitoring the intracranial pressure.

16. The method of claim 10, whereby said characteristic monitored is selected from the group consisting of pH, partial oxygen pressure, temperature, carbon dioxide concentration, and combinations thereof.

17. The method of claim 16, whereby the pH of said CSF is monitored and compared with a base line.

18. The method of claim 10, further comprising:

monitoring said characteristic on a continuous basis;

storing said data; and

comparing said data.

19. The method of claim 10, whereby said monitoring step comprises:

monitoring said characteristic within the initial 24 hours following trauma.

20. The method of claim 19, whereby said monitoring step comprises:

monitoring said characteristic within the initial 48 hours following trauma.

21. A method of monitoring at least one characteristic of cerebrospinal fluid (CSF) of a patient for prognosis and for providing information for treatment, comprising:

providing an opening in said patient through which a region of CSF is accessible;

inserting a catheter through said opening into said region of CSF in said patient, said catheter having a flow section capable of permitting said CSF to flow therein;

positioning said flow section of said catheter into said region of CSF;

placing a sensor into said flow section within said catheter to enable said CSF to flow adjacent the tip of said sensor so that said sensor may sense at least one characteristic of said CSF; and

monitoring the changes of said characteristic of said CSF.

22. The method of claim 21, further comprising:

fixing said catheter in place in said opening of said patient to prevent movement of said catheter relative to said opening in said patient.

23. The method of claim 21, whereby said inserting step further comprises:

inserting said catheter into said region of CSF until expression of said CSF indicates said catheter has reached said region of CSF.

24. The method of claim 21, further comprising:

connecting said catheter to an extension tube; and

locking said sensor within said catheter.

25. The method of claim 24, further comprising:

draining said CSF through said catheter.

26. The method of claim 21, whereby said characteristic monitored is selected from the group consisting of pH, partial oxygen pressure, temperature, carbon dioxide concentration, and combinations thereof.

27. The method of claim 26, whereby the pH of said CSF is monitored and compared with a base line.

28. The method of claim 21, further comprising:

monitoring said characteristic on a continuous basis;

storing said data; and

comparing said data.

29. The method of claim 21, whereby said monitoring step comprises:

monitoring said characteristic within the initial 24 hours following trauma.

30. The method of claim 29, whereby said monitoring step comprises:

monitoring said characteristic within the initial 48 hours following trauma.

31. An apparatus for monitoring the cerebral cellular environment of a patient, comprising:

a catheter having a wall section adapted to permit cerebrospinal fluid (CSF) to flow therein, said catheter adapted for introduction through an opening in a skull of a patient; and

a sensor located within said catheter such that said CSF is permitted to flow adjacent the tip of said sensor;

whereby said sensor is capable of permitting the monitoring of at least one characteristic of said CSF over time.

32. The apparatus of claim 31, whereby said catheter is a dual lumen catheter comprising a first lumen and a second lumen.

33. The apparatus of claim 32, whereby said sensor is housed in said first lumen and said CSF is withdrawn through said second lumen.

34. The apparatus of claim 31, whereby said characteristic monitored is selected from the group consisting of pH, partial oxygen pressure, temperature, carbon dioxide concentration, and combinations thereof.

35. The apparatus of claim 31, further comprising:

equipment for monitoring, storing, and, comparing data of said characteristic from said sensor over time.

36. An apparatus for monitoring at least one characteristic of cerebrospinal fluid (CSF) of a patient, comprising:

a catheter having a wall section adapted to permit said CSF to flow therein, said catheter adapted for introduction through an opening in said patient through which a region of CSF is accessible; and

a sensor located within said catheter such that said CSF is permitted to flow adjacent the tip of said sensor;

whereby said sensor is capable of permitting the monitoring of at least one characteristic of said CSF over time.

37. The apparatus of claim 36, whereby said catheter is a dual lumen catheter comprising a first lumen and a second lumen.

38. The apparatus of claim 37, whereby said sensor is housed in said first lumen and said CSF is withdrawn through said second lumen.

39. The apparatus of claim 36, whereby said characteristic monitored is selected from the group consisting of pH, partial oxygen pressure, temperature, carbon dioxide concentration, and combinations thereof.

40. The apparatus of claim 36, further comprising:

equipment for monitoring, storing, and, comparing data of said characteristic from said sensor over time.